

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 03-31V

Filed: May 21, 2014

THOMAS J. BLAKE, and
PAMELA L. BLAKE, legal representatives
of a minor child, W.J.B.,

Petitioners,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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Autism; Ruling on the Record;
Lack of Factual Predicate for a
Table Encephalopathy;
Insufficient Proof of Causation

Michael L. Cave, Cave Law Firm, Baton Rouge, LA, for petitioners.

Voris E. Johnson, Jr., U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

Vowell, Chief Special Master:

On January 7, 2003, Thomas and Pamela Blake [“petitioners”] filed a petition for vaccine injury compensation under the National Childhood Vaccine Injury Act² [“Vaccine Act”] on behalf of their son, W.J.B. Petitioners alleged that the vaccines W.J.B. received on December 13, 1999 and January 4, 2000 caused an “encephalopathic pattern of change characteristic of the autism spectrum.” Petition at 1. Petitioners also

¹ This decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to redact medical or other information, that satisfies the criteria in 42 U.S.C. § 300aa-12(d)(4)(B). If, upon review, I agree that the identified material fits within the requirements of that provision, I will redact such material from public access.

² The National Vaccine Injury Compensation Program [“Program”] comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et seq. (2006). All citations to the Vaccine Act in the decision will be to 42 U.S.C. § 300aa.

contended “that [W.J.B.] suffered mercury poisoning which was caused-in-fact by the thimerosal present in the vaccines he received since birth.” *Id.*, ¶ 17.

On September 14, 2011, petitioners filed an amended petition, alleging that W.J.B. suffered “the table injury known as encephalopathy” after receiving the measles, mumps, and rubella [“MMR”] vaccine on January 4, 2000. Amended Petition [“Am. Petition”] at 1. The amended petition now constitutes the operative petition for petitioners’ vaccine injury claim. However, in their motion for a ruling on the record petitioners also asserted that the MMR vaccine actually caused W.J.B.’s injuries.³ I will treat these assertions as raising a causation in fact claim and, thus, this decision also resolves any off-Table (actual causation) injury claim petitioners have made.

The case is now ripe for a decision. In order to prevail under the Program, petitioners must prove either that W.J.B. sustained a “Table” injury⁴ or that a vaccine listed on the Table was the cause in fact of an injury. The record as a whole fails to demonstrate that W.J.B. suffered a Table injury or that a vaccine caused his autism spectrum disorder.⁵ Petitioners’ vaccine injury claims are therefore dismissed.

I. Procedural History.

A month after petitioners filed their original petition, their claim was, without objection, included in the Omnibus Autism Proceeding [“OAP”].⁶ Their case was

³ Petitioners argued both a Table Injury claim and actual causation claim in their motion for a decision on the record and reply. See Petitioners’ Motion for a Decision on the Record [“Pet. Motion”] at 1 (asserting that they had established a “prima facie case” that W.J.B.’s encephalopathy was caused by the MMR vaccination); Petitioners’ Reply in Support of Pet. Motion [“Pet. Reply”] at 3-4 (arguing that they proved W.J.B.’s encephalopathy was caused by the MMR vaccine); Petitioners’ Statement of Proposed Findings of Fact [“Pet. Facts”] at 2-3 (proposed statement of facts including that physicians had opined that W.J.B.’s encephalopathy was causally and temporally connected to the MMR vaccination); see *also* Petitioners’ Memorandum in Support of Motion for Decision on the Record [“Pet. Memo”] at 6 (commenting that a physician had opined that it was more probable than not that the MMR vaccine caused W.J.B.’s encephalopathy). As proof of causation is unnecessary if the factual requirements for a Table injury have been established, I have elected to treat these assertions as raising a causation in fact claim.

⁴ A “Table” injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified.

⁵ Pervasive developmental disorder [“PDD”] was the umbrella term for autism spectrum disorders used in the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 4th ed. text revision 2000) [“DSM-IV-TR”]. The DSM-IV-TR has since been replaced by the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 5th ed. 2013) [“DSM-V”] which uses the term “autism spectrum disorder” [“ASD”].

⁶ See Notice, issued Feb. 10, 2003. A more detailed discussion of the OAP can be found at *Dwyer v. Sec’y, HHS*, No. 03-1202V, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

effectively stayed while general causation issues were litigated in the OAP test cases.⁷

During the period between the test case hearings and final appellate action in the test cases, petitioners were ordered to file the medical records necessary to establish that the petition was timely filed. Order, issued Apr. 15, 2008, at 2-5. After petitioners filed medical records on July 11, 2008, as Petitioners' Exhibits ["Pet. Exs."] 1-13, respondent filed a statement acknowledging that the claim was timely filed and the injury involved an autism spectrum disorder. Respondent's Statement, filed Aug. 25, 2008, at 3. Following resolution of the OAP test cases,⁸ petitioners opted to continue their claim.

On October 5, 2011, the special master formerly assigned to the case⁹ held a conference call with the parties to discuss the amended petition. See Order, issued Oct. 5, 2011, at 1. During the call, the special master referenced the definition of acute encephalopathy contained in the Qualifications and Aids to Interpretation ["QAI"] section of the Vaccine Injury Table (see 42 C.F.R. § 100.3(b)(2)(i))¹⁰ and noted the "potential difficulty associated with characterizing symptoms that commonly manifest as symptoms of autism as symptoms that are indicative of an acute encephalopathy." Order, issued Oct. 5, 2011, at 1.

In a status report filed on November 3, 2011, petitioners indicated they planned to file an expert report from W.J.B.'s treating physician Dr. Gerald Erenberg, a pediatric and adolescent neurologist, and a second expert report from an "independent" medical

⁷ The Petitioners' Steering Committee ["PSC"], an organization formed by attorneys representing petitioners in the OAP, litigated six test cases presenting two different theories on the causation of autism spectrum disorder ["ASDs"]. Petitioners' original claim fell within the second theory of causation ["Theory 2"] litigated in the OAP. Their causation in fact claim implicates the first causation theory ["Theory 1"] advanced in the OAP test cases.

⁸ Decisions in each of the three test cases pertaining to the PSC's first theory rejected petitioners' causation theories. *Cedillo v. Sec'y, HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y, HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y, HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). Decisions in each of the three "test cases" pertaining to the PSC's second theory also rejected the causation theories, and petitioners in each of the three cases chose not to appeal. *Dwyer*, 2010 WL 892250; *King v. Sec'y, HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y, HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

⁹ This case was formerly assigned to Chief Special Master Campbell-Smith. Prior to her appointment as Judge of the United States Court of Federal Claims, the case was reassigned to me. President Obama designated Judge Campbell-Smith as Chief Judge of the Court of Federal Claims on October 21, 2013.

¹⁰ The QAI to the Vaccine Injury Table are located at 42 C.F.R. § 100.3(b) and contain definitions for the terms used in the Table. See *Althen v. Sec'y, HHS*, 58 Fed. Cl. 270, 280 (2005), *aff'd*, 418 F.3d 1274 (Fed. Cir. 2005) (noting that the QAI should be used to interpret key terms found in the Table).

expert, Dr. Stephanie F. Cave,¹¹ a family practice physician. Status Report at 1. Petitioners never filed an expert report from Dr. Erenberg, but did file Dr. Cave's expert report on November 30, 2011.

Due to "a lack of documentary support for the factual allegations" in Dr. Cave's report, the special master ordered petitioners to file a supplemental report, referencing the exhibit and page number of records supporting her factual assertions and including details regarding her "relevant training and professional experiences." Order, issued Dec. 12, 2011, at 1, n.1. Petitioners filed Dr. Cave's supplemental expert report on January 16, 2012, as Pet. Ex. 15.¹²

In a lengthy order issued on February 15, 2012, the special master discussed Dr. Cave's lack of expertise in the relevant specialties of developmental pediatrics, pediatric neurology, or pediatric immunology, and the lack of evidence of a Table encephalopathy. Order at 1-4. She observed that "the symptoms of concern seem to be completely consistent with the early symptoms of autism." *Id.* at 6. She indicated that "[a]t present, the factual record and Dr. Cave's expert report fall short of establishing that [W.J.B.] suffered a MMR vaccine-related encephalopathy as defined by the Vaccine Injury Table" and questioned the reasonableness of moving forward on that theory. *Id.* at 7.

Notwithstanding the special master's concerns, petitioners reiterated that they wished to continue their claim. Status Report, filed Mar. 16, 2012. Following some difficulty in communication between petitioners and their attorney (see Order to Show Cause, issued July 10, 2012), a fact hearing was set for November 14, 2012 (Order, issued Sept. 13, 2012).

Only petitioners testified at the hearing, but affidavits from Mrs. Blake's sister, Debbie Knopf, and W.J.B.'s great aunt, Patricia Blake, were filed as Pet. Exs. 25-26. Prior to the hearing, petitioners also filed their joint affidavit (Pet. Ex. 14), pages from a journal kept by petitioners (Pet. Ex. 16), two videos of W.J.B. (Pet. Exs. 18A and 18B),¹³ notes describing the video clips (Pet. Ex. 17),¹⁴ photographs of W.J.B. (Pet. Ex. 19),

¹¹ Doctor Cave is the mother of petitioners' counsel, Michael Cave. See *Mooney v. Sec'y, HHS*, No. 05-266V, 2013 WL 3874444, at *3, 4 n.14 (Fed. Cl. Spec. Mstr. July 3, 2013).

¹² Petitioners did not assign an exhibit number to Dr. Cave's initial expert report. However, the supplemental report is virtually identical to the initial report, other than the addition of paragraph 2 and citations to medical records. All citations to Dr. Cave's report are to the supplemental version filed as Pet. Ex. 15.

¹³ Petitioners filed the first video, labeled as Pet. Ex. 18, on October 4, 2012. The docket does not indicate exactly when the second video was received by the court but a notice indicating the video was mailed was electronically filed on November 5, 2012. Although the second video was labeled as Pet. Ex. 18, Part 2, I will refer to the first video as Pet. Ex. 18A and second video as Pet. Ex. 18B.

¹⁴ Petitioners provided handwritten notes (Pet. Ex. 17), ostensibly describing what the video clips

additional medical records (Pet. Exs. 20-24), and one medical journal article¹⁵ (Pet. Ex. 27). Respondent's counsel indicated he would not be calling any witnesses. Respondent's Pre-Hearing Submission, filed Oct. 3, 2012, at 1.

In a post hearing status conference, the special master discussed her impressions with the parties and issued a lengthy order summarizing the matters discussed. See Order, issued Jan. 23, 2013. She indicated that she was "prepared to accept as true, the claim that [W.J.B.] exhibited startles that may have been seizure-related during the occasion of the family meal" on January 9, 2000. *Id.* at 2. Nevertheless, she concluded that there was insufficient evidence to demonstrate that W.J.B. had experienced a Table encephalopathy.¹⁶ *Id.* Informing the parties that she "consider[ed] the record to be factually complete, and amenable to a summary judgment motion," the special master urged petitioners to file a motion for a decision, explaining they could file a motion for a decision on the record, in which they could include a proposed set of facts, or a motion to dismiss their claim. *Id.* at 3.

The case was reassigned to me on March 8, 2013. On April 4, 2013, petitioners filed a motion for a decision on the record, along with several supporting memoranda.¹⁷ Approximately six weeks later, respondent filed her response, along with two medical journal articles on the symptoms and diagnosis of ASDs and three excerpts of testimony from the OAP. See Respondent's Exhibits ["Res. Exs."] A-E.

Although petitioners did not precisely object to respondent's evidence, they described it as filed after "the deadline to submit evidence." Pet. Reply at 1.

depicted. I will refer to these notes as the video narrative. However, the video narrative sometimes describes events not depicted on the video and, on occasion, inaccurately describes what appears on the video clips. Where there are conflicts, I rely primarily on the video clips, rather than the narrative.

¹⁵ G.R. Delong, et al, *Acquired Reversible Autistic Syndrome in Acute Encephalopathic Illness in Children*, 38(3) ARCH NEUROL 191-94 (1981). This article, which is more than three decades old, reports on three cases of late onset of autistic symptoms (at 5, 7 ½, and 11 years of age) in conjunction with "an acute encephalopathic illness." *Id.* at 193. None of the illnesses were attributed to a vaccination. One of the children was diagnosed with encephalitis caused by a herpes virus infection. *Id.* at 192. Whether an acute encephalopathy caused by illness can present with symptoms similar to autism does not appear to be in issue; rather, the issue in this case is whether W.J.B. had symptoms consistent with an acute encephalopathy following the allegedly causal vaccinations. Thus, I did not find this article relevant to the issues in dispute.

¹⁶ During the status conference, the special master once again reviewed the definition of a Table encephalopathy as set forth in the QAI section of the Vaccine Injury Table. When petitioners' counsel argued that the definition found in the QAI would not be acceptable to the medical community at large, the special master observed that the narrower definition in the Table was intentionally more restrictive. *Id.*; see also *infra* discussion at Section II.D.2. She noted that petitioners' counsel seemed to be arguing for a change to the QAI definition, a request that she could not grant. Order, issued Jan. 23, 2013, at 2.

¹⁷ See *supra*, note 3.

Petitioners' description is incorrect. The special master formerly assigned to the case imposed a deadline in October 2012 for documents upon which the parties intended to rely during the November 2012 fact hearing. See Order, issued Sept. 13, 2012, at 2. This deadline did not preclude the parties from filing evidence after the fact hearing that related to issues raised during the hearing or in subsequent filings. Moreover, petitioners indirectly raised an actual causation claim in their April 4, 2013 motion and supporting documents and did so more explicitly in their reply to respondent's filings. See Pet. Reply at 3-4. Under these circumstances, it was appropriate for respondent to file additional evidence as a part of the ruling on the record process.

However, *sua sponte*, I have elected to disregard Res. Ex. D, the excerpt of the OAP testimony of Dr. Max Wiznitzer. Doctor Wiznitzer was one of W.J.B.'s treating physicians at a time prior to presenting his OAP testimony. See Pet. Ex. 6, pp. 1-4. (records reflecting Dr. Wiznitzer's treatment). Although it does not appear that W.J.B. is still one of Dr. Wiznitzer's patients and Dr. Wiznitzer's OAP testimony did not involve W.J.B.'s care and treatment, to avoid any potential or actual conflict of interest for Dr. Wiznitzer, I will not consider his OAP testimony.

This case is now ready for a decision. In Section II, I set forth the evidence regarding W.J.B.'s health and development prior to his MMR vaccination and the symptoms he manifested in the relevant period after the vaccination, the requirements to establish a Table injury, and my conclusions regarding the Table injury claim. In Section III, I discuss the evidence for actual causation.

Having considered the record as a whole, I find that petitioners have failed to establish the factual predicate for a Table injury. I hold that they have failed to demonstrate by preponderant evidence that the MMR vaccination actually caused W.J.B.'s autism spectrum disorder.

II. The Table Injury Claim.

A. Summary.

The evidence regarding W.J.B.'s condition prior to and following the MMR vaccination on January 4, 2000 is conflicting, but the fact that W.J.B. exhibited some symptoms consistent with an ASD after his MMR vaccination is not disputed. Petitioners described the symptoms as "encephalopathic changes," arguing that W.J.B. suffered a Table encephalopathy.¹⁸ Pet. Motion at 1; see *also* Pet. Reply at 1-3 (petitioners contrasting autism and encephalopathy). Asserting that petitioners' claim of

¹⁸ As addressed in more detail below, petitioners persistently conflate the terms "encephalopathy" and "encephalopathic" with the term "encephalopathy" as defined in the Vaccine Injury Table. Within the context of a Table injury claim, "encephalopathy" is a term of art, with a very specific definition. In logic's terminology, all Table encephalopathies are encephalopathies, but only some encephalopathies meet the exacting Table definition.

a Table encephalopathy is unsupported by the evidence, respondent described W.J.B.'s symptoms as "subtle and consistent with the emergence of an autism spectrum disorder." Respondent's Response to Pet. Motion ["Res. Response"] at 7.

Respondent's assertions are supported by the evidentiary record; for the most part, petitioners' assertions are not. In contrast to the often subtle onset of behaviors associated with ASDs, there is little that is subtle about an acute encephalopathy that meets the Table definition of this condition. It is a condition that is so serious as to require hospitalization, whether or not hospitalization actually occurred. 42 C.F.R. § 100.3(b)(2)(i).

Even accepting petitioners' hearing testimony and affidavits as true and correct regarding W.J.B.'s condition at the relevant time periods (between January 9-19, 2000 for onset of an acute Table encephalopathy and for the six months thereafter for a chronic Table encephalopathy), their evidence falls far short of that necessary to establish that W.J.B. sustained either an acute or chronic Table encephalopathy. Other evidence of record, including petitioners' own journal, video records, and medical records, make plain that W.J.B. never met the requirements for an acute Table encephalopathy.

B. Requirements for a Table Encephalopathy.

To establish an MMR-Table encephalopathy, petitioners must demonstrate W.J.B. suffered an "encephalopathy" as defined by the QAI section to the Vaccine Injury Table within five to fifteen days of his MMR vaccination. 42 C.F.R. § 100.3(a). Since W.J.B. received the MMR vaccine on January 4, 2000, petitioners must establish the onset of a Table encephalopathy during the period from January 9 to 19, 2000.

1. The Table Definitions.

According to the QAI, a vaccinee is considered to have suffered a Table encephalopathy if the vaccinee manifests an injury encompassed in the definition of an acute encephalopathy within the appropriate time period, and if a chronic encephalopathy is present for more than six months after the immunization. 42 C.F.R. § 100.3(b)(2).

An acute encephalopathy is "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." 42 C.F.R. § 100.3(b)(2)(i). For a child younger than 18 months of age,¹⁹ presenting without an associated seizure event, an acute encephalopathy is indicated "by a significantly decreased level of consciousness . . . lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i)(A). A

¹⁹ W.J.B. was not 18 months old until January 24, 2000, placing his case in the "younger than 18 months" period for purposes of evaluating whether he experienced an acute encephalopathy.

significantly decreased level of consciousness is indicated by the presence of one of three clinical signs for a period of at least 24 hours: “(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).” 42 C.F.R. § 100.3(b)(2)(i)(D). Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle are not, alone, or in combination, a demonstration of an acute encephalopathy. 42 C.F.R. § 100.3(b)(2)(E).

A chronic encephalopathy is defined in the QAI as “a change in mental or neurologic status, first manifested during the applicable time period, [that] persists for a period of at least 6 months from the date of vaccination.” 42 C.F.R. § 100.3(b)(2)(ii). If a person returns to a typical neurologic state after suffering an acute encephalopathy, he or she is not presumed to have suffered residual neurologic damage and “any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy.” *Id.*

2. Analysis of the Table Requirements.

“The symptoms associated with an acute encephalopathy are neither subtle nor insidious.” *Waddell v. Sec’y, HHS*, 2012 WL 4829291, at *6 (Fed. Cl. Spec. Mstr. Sept. 19, 2012). As noted in *Waddell*, “[t]he hospitalization requirement underscores how serious the symptom presentation must be after vaccination to merit classification as a Table encephalopathy.” 2012 WL 4829291, at *7 (citing to Revision of the Vaccine Injury Table, 60 Fed. Reg. 7,685, 7,687 (Feb. 20, 1997) (preamble to final rule) (“[W]e did not intend that hospitalization be viewed as an absolute requirement to establish an acute encephalopathy, but rather as an indicator of the severity of the acute event.”)).

The descriptions of the clinical signs added to the QAI also illustrate the severity of the symptoms required to demonstrate acute encephalopathy. See 42 C.F.R. § 100.3(b)(2)(i)(D). In amending the QAI, the Secretary of Health and Human Services²⁰ included the specific clinical signs at 42 C.F.R. § 100.3(b)(2)(i)(D) in an effort to “clearly distinguish infants and children with brain dysfunction from those with transient ‘lethargy,’” noting that the severity and duration of “more serious impairment of consciousness that is the hallmark of encephalopathy” differentiated it from the “diminished alertness and motor activity” of lethargy following a fever or illness. 60 Fed. Reg. 7678, 7687 (Feb. 8, 1995). The “‘significantly decreased level of consciousness’ [required in the QAI definition] refers to a state of diminished alertness that is much more than mere sleepiness or inattentiveness.” *Waddell*, 2012 WL 4829291, at *7.

²⁰ See Revision of the Vaccine injury Table, 60 Fed. Reg. 7678, 7679-80 (Feb. 8, 1995) (discussing the Secretary’s authority to modify both the Vaccine Table and QAI section).

In contrast, encephalopathy²¹ as commonly used in the medical community encompasses a much broader class of injuries than the more stringent definition of acute encephalopathy found in the QAI. As explained in *Waddell*, “[t]he scope of the medical term ‘encephalopathy’ is more expansive than the narrower, statutory definition set forth in the Table.” 2012 WL 4829291, at *12 (referencing *Hazelhurst*, 2009 WL 332306, at *26-29). The QAI definition of acute encephalopathy simply does not encompass every type of brain dysfunction to which the broader meaning of “encephalopathy” applies.

C. Evidence Regarding W.J.B.’s Condition During the Relevant Time Frames.

1. Facts Not Reasonably Subject to Dispute.

W.J.B.’s birth on July 24, 1998 and early childhood were essentially normal. He received the usual childhood vaccinations at two, four, six, nine, 12, and 17 months of age without apparent ill effects. Pet. Ex. 1, pp. 4-9. He suffered from several childhood illnesses, including an upper respiratory infection (URI) at about three weeks of age, and similar illnesses on several other occasions after six months of age. He also had a number of ear infections. See Pet. Exs. 1, pp. 2, 11-15; 12, p. 1. At 16 months of age, he was diagnosed with allergic rhinitis. Pet. Ex. 1, p. 14.

On two occasions in early childhood, W.J.B. failed to meet a developmental milestone. Pet. Ex. 1, p. 7 (did not pull to stand at nine months of age); p. 8 (did not use a cup at twelve months of age). Otherwise, he appeared to be developing normally through about 17 months of age. See *generally, id.*, pp. 1-15. He met all developmental milestones at a well child visit on December 19, 1999, at about 17 months of age, including speaking three to six words. His behavior was assessed as normal, but he reportedly suffered from night terrors. *Id.*, p. 9. He received several vaccinations at this visit, but his initial MMR vaccination was postponed until after the holidays. *Id.*, pp. 1, 9.

Just prior to the administration of W.J.B.’s MMR vaccination, both of his parents had a flu-like illness with vomiting and diarrhea. It is not entirely clear from the records and testimony whether W.J.B. was ill, too, or merely tired and irritable.²² However, after examining W.J.B. on January 4, 2000, his pediatrician noted he was alert and playful, and concluded that he could receive the MMR vaccine. Pet. Ex. 1, p. 15.

²¹ Encephalopathy is defined very broadly as “any degenerative disease of the brain.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY [“DORLAND’S”] (32nd ed. 2012) at 614.

²² Petitioners first asserted that W.J.B. had the flu prior to receiving his MMR vaccination. Am. Petition, ¶ f; Pet. Ex. 14, ¶ e; Pet. Exs. 2, p. 1; 6, p. 1; 12, p. 1; 23, p. 1. In her expert report, Dr. Cave refers to “an uncomplicated episode of a viral illness,” prior to W.J.B.’s receipt of the MMR vaccine. Pet. Ex. 15 at 1. Later, petitioners claimed W.J.B. did not have the flu. Tr. at 15-18, 121-23; see also Attachments to Pet. Motion for Decision: Pet. Facts at 4-5, 8; Pet. Memo. at 3-4.

2. The Evidence Regarding W.J.B.'s Condition after the MMR Vaccination.

The evidentiary record regarding W.J.B.'s condition after the allegedly causal vaccination is conflicting. Assuming, *arguendo*, that petitioners' testimony and affidavit correctly reflect the symptoms W.J.B. displayed and timing of these symptoms, their evidence, as the previous special master noted after the hearing, fails to establish that W.J.B. sustained an acute Table encephalopathy during the relevant period.

a. Petitioners' Testimony and Affidavits.

Petitioners testified that the first symptom of W.J.B.'s encephalopathy, two shuddering episodes, occurred at a family dinner on January 9, 2000. This date is the first date of the five to fifteen day time period during which a Table injury must manifest

Petitioners claim that by the end of time period (January 19, 2000), W.J.B. exhibited numerous symptoms of a Table encephalopathy. In their amended petition, petitioners asserted "[o]ver the next several weeks, and by January 19, 2000, [W.J.B.] had difficulties responding to his name, decreased eye contact, perseverative behavior, decreased speech, increased crying, decreased smiling and laughing, sleep problems, selective eating, asocial behavior, and did not look happy" (Am. Petition, ¶ i). With some variations and a few omissions, petitioners repeated these claims in their affidavit, adding that W.J.B. also "had a marked decrease in coordination, increased sensitivity to sounds," and was less responsive to his parents and objects or people in his environment. Affidavit, ¶ h.

Although petitioners described similar symptoms during their testimony, they often indicated they did not notice a particular symptom until days or even weeks after January 19, 2000. For example, Mrs. Blake testified that she did not notice many of W.J.B.'s symptoms until she experienced a "very clear manifestation" on January 31, 2000, that W.J.B.'s communication, motor control, and social relationships were different.²³ Tr. at 63.

Petitioners testified that over the remainder of January 2000 and beyond, W.J.B. became less social (Tr. at 61-63, 81-82, 163), less responsive to them and others (Tr. at 56, 60), had decreased eye contact (Tr. at 56), lost language skills (Tr. at 56, 63, 68, 141-42), began head-banging (Tr. at 64-68, 138-40), experienced a deterioration in motor skills (Tr. at 63, 137-38), exhibited perseverative behaviors (Tr. at 56-57, 60, 68, 81-82, 138), had difficulty sleeping (Tr. at 87, 159), was more irritable, screamed and cried (Tr. at 56, 87, 155), and became a picky eater (Tr. at 58, 140-41).

²³ Mrs. Blake testified that on January 31, 2000 she was struck by the similarities between W.J.B.'s behavior and the actions of three of the residents at the adult group home where she was working as an occupational therapist. Tr. at 62-63.

b. Other Evidence.

If petitioners' own testimony does not make their Table injury claim untenable, other evidence certainly does. The medical records, videos of W.J.B. during the period when the Table encephalopathy allegedly occurred, and petitioners' own journal conclusively demonstrate that there was no Table encephalopathy. Rather, W.J.B. continued to manifest symptoms of an ASD, including the intensifying of some symptoms displayed prior to the MMR vaccination.

(1) Medical Records.

W.J.B. did not visit his pediatrician for nearly four weeks after his MMR vaccination on January 4, 2000. Thus, there were no medical records created during the five-to fifteen-day period after vaccination. There were, however, medical records documenting other illnesses within two to three months of the MMR vaccination which are remarkable in their lack of any mention of symptoms consistent with an acute Table encephalopathy in mid-January 2000.

On January 31, 2000, Mrs. Blake called the pediatrician's triage center because W.J.B. had experienced two days of a low-grade fever and had a loose cough, a runny nose, and reduced oral intake. Pet. Ex. 1, p. 20. She was advised to call back if his fever lasted for more than three days, if there was thick, yellow nasal discharge for longer than 48 hours, if there was clear nasal discharge lasting more than 10 days, or if W.J.B. became worse. *Id.*

The next day, on February 1, 2000, W.J.B.'s symptoms continued and he was seen by his pediatrician. Pet. Ex. 1, p. 15. At the visit he was observed to be alert and playful, but was diagnosed with another ear infection. *Id.*

Two days later, on February 3, 2000, W.J.B.'s mother called the triage center because W.J.B. had been "ill all week." Pet. Ex. 1, p. 21. He was afebrile, but was moaning and crying. Petitioners requested to speak to a doctor as Mr. Blake felt W.J.B. was getting worse and were advised to take W.J.B. to the emergency room. They returned home from the emergency room without being seen because there was a two hour wait. At home, Mr. Blake placed another call to the triage center, spoke to a physician, and indicated that he and Mrs. Blake felt W.J.B. could be seen again in the morning.²⁴ Pet. Ex. 1, p. 21.

On February 4, W.J.B.'s pediatrician examined him and diagnosed him with sinusitis. Pet. Ex. 1, p. 15. He also documented a concern about W.J.B.'s speech. The entry indicated that the pediatrician intended to discuss speech concerns at a follow up

²⁴ During hearing, Mrs. Blake testified that she did not remember this incident clearly. Tr. at 74.

visit. *Id.*, p. 15. In early March 2000, the pediatrician referred W.J.B. to the Cleveland Clinic for Hearing and Speech. *Id.*, p. 16.

On February 24, 2000, Mrs. Blake called the triage center because W.J.B. had vomited. Pet. Ex. 1, p. 22. She indicated that W.J.B. did not have a seizure, had eaten well that day, and was afebrile and voiding but that he “does hit his head” on the wall or floor during temper tantrums. *Id.* This was the first mention of “head-banging” in W.J.B.’s medical records, although a journal entry from January 24 mentions a head-banging incident.²⁵ Mrs. Blake relayed that W.J.B. “ha[d] a bruise on his forehead” but was “playful.” Pet. Ex. 1, p. 22. The vomiting was assessed as viral gastritis and Mrs. Blake was instructed to apply ice to W.J.B.’s head, call back if pain persisted for more than 20 minutes, and to follow-up with his primary care physician.

Approximately an hour later, Mr. Blake called back, indicating he had called 911 after W.J.B. vomited again. Although the emergency medical service (EMS) provider was present and believed W.J.B. to be fine, Mr. Blake requested to speak to a doctor. W.J.B. was seen by his pediatrician the next day and diagnosed with another ear infection.²⁶ Pet. Ex. 1, p. 16. During that visit, his parents reported that he had been head banging for two weeks. *Id.* This would place onset of W.J.B.’s head banging at around February 10, 2000, although the journal entry for January 24, 2000 reflected an earlier incident. Pet. Ex. 16 at 3.

In mid-March, Mrs. Blake reported more troubling behavior by W.J.B. She described him as being inactive, staring at lights, pulling at his sleeves, and hiding in the closet. Pet. Ex. 1, p. 26. On April 8, 2000, W.J.B.’s parents brought him to the pediatrician because he was exhibiting behaviors consistent with PDD and obsessive compulsive disorder [“OCD”]²⁷ and had been less responsive to them during the past week. They also described a decrease in language. Pet. Ex. 1, p. 16. They indicated the “PDD like behavior started since January after [the] MMR [vaccination].” *Id.* W.J.B. was referred for a behavioral health evaluation. *Id.* He underwent an occupational therapy evaluation on April 22, 2000 and began receiving occupational therapy. Pet. Ex. 3, p. 1.

²⁵ Pet. Ex. 16 at 13. According to the journal entry, W.J.B. banged his head when Mrs. Blake would not allow him to play with electrical cords.

²⁶ The antibiotics prescribed for W.J.B.’s ear infection caused him to develop diarrhea. See Pet. Ex. 1, p. 25. After a few days, W.J.B.’s parents took him back to the pediatrician, who diagnosed enteritis. Pet. Ex. 1, p. 16. Enteritis is an intestinal inflammation characterized by vomiting and lethargy. DORLAND’S at 624.

²⁷ OCD is an anxiety disorder characterized by recurrent obsessions or compulsions that are severe enough to interfere significantly with personal or social functioning. Performing compulsive rituals may release tension temporarily, and resisting them causes increased tension. DORLAND’S at 551.

b. Video Records²⁸ and Petitioners' Journal.

The video evidence stands in sharp contrast to petitioners' claims. There are no significant differences in W.J.B.'s behavior before and after his MMR vaccination depicted on the videos from November 1999 to January 2000. Likewise, petitioners' journal entries reflect a child who was engaged with his parents and his environment throughout January 2000.

Journal entries from January 2000, and, in particular, those from January 9-19, unequivocally contradict petitioners' claims. Rather than describing a child with a significantly decreased level of consciousness, these entries contain multiple references to W.J.B. dancing, singing, laughing, asking for things, learning new colors or words, and noticing when his blue block was missing. Pet. Ex. 16 at 10-12. There are also entries reflecting W.J.B.'s responses to his environment. He cried when another child took his blue block (on January 6), when his mother "flew" another child (on January 7), when left with a babysitter (on January 8, 15, and 23), when his mother tried to give him a noodle from her soup (on January 10), when his father went to work (on January 12 and 26), and when the doorbell rang (on January 15). *Id.* at 10-13.

W.J.B. did not talk much on any of the video clips. However, petitioners' journal contradicts Mrs. Blake's testimony regarding W.J.B.'s use of words during the period after his MMR vaccination. From January 9-19, there are entries indicating that W.J.B. was speaking and no indication that he was experiencing a loss of language skills. The journal records W.J.B. asking for more "milk" on January 12 (Pet. Ex. 16 at 11) and learning the words "more" and "up" on January 18 (*id.* at 12).

In video clips recorded before and after vaccination, W.J.B. ignored his parents' attempts to get his attention. Pet. Ex. 18A at 14:28-16:10, 22:10-23:47, 24:02-25:41. Contrary to assertions that he was unresponsive to his parents, the January 15 video clip reflects that W.J.B. was excited and responded to his father when Mr. Blake mentioned the "Irish Trot." Pet. Ex. 18A at 27:17-29.

The journal contains several notations of behaviors that might be indicative of an emerging ASD diagnosis. However, none of the journal entries in January 2000 reflect a child who had ceased interacting with his parents or environment. He was described as tired on January 11, and "not too excited" and "pretty quiet" on the evening of January 19 at Gymboree. Pet. Ex. 16 at 11-12. However, on both days, W.J.B. also was described as singing, slow dancing, playing independently with toys, and pointing to the refrigerator for his "bedtime bottle" (on January 11) and waving "Bye-Bye to Daddy" in the morning, having the giggles with mommy when she blew on his feet, liking

²⁸ Although the record contains photographs as well as video evidence, the photographs do not provide evidence about W.J.B.'s language abilities, motor skills, or social skills. Although I have examined them, they are not otherwise discussed in this decision.

the stuffed blue bear, exploring doors and cupboards, enjoying the bubble lights, crawling in the ball pit, and becoming jealous of his mother's friend's baby (on January 19). *Id.*

E. Evaluating Petitioners' Table Encephalopathy Claim.

Conflicts between contemporaneous medical records and subsequent statements are common in Vaccine Act cases, with special masters frequently according more weight to the symptoms contemporaneously recorded, rather than those recounted in later medical histories, affidavits, or trial testimony. "It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." *Murphy v. Sec'y, HHS*, 23 Cl. Ct. 726, 733 (1991); see also *Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by "clear, cogent, and consistent testimony" explaining the discrepancies. *Stevens v. Sec'y, HHS*, No. 90-221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr. Dec. 21 1990).

Petitioners argue that W.J.B.'s shuddering episodes and behavioral symptoms began between January 9-19, 2000, and by January 19 constituted at least one of the clinical signs of the significantly decreased level of consciousness required by the QAI definition of an acute encephalopathy. Pet. Motion at 1. Even if I accepted their testimony as accurately depicting W.J.B.'s condition and behavior during the January 2000, these symptoms are insufficient to meet the acute Table encephalopathy requirements, although they may well be indicative of the emergence of his ASD. I make the following factual findings and conclusions of law regarding the Table injury claim.

1. Factual Findings.

a. W.J.B. experienced two "shuddering" episodes at a family dinner on January 9, 2000, but his parents did not consider them serious, as they did not seek any medical attention at all for W.J.B. until 22 days later, and did not mention the episodes to his physician at this medical visit, the one closest in time to their occurrence.

b. There is no evidence that these shuddering episodes were seizure-related. His physician called them "baby stress" when they were first described to a medical professional months later.²⁹ Ms. Patricia Blake, a nurse-practitioner and

²⁹ The shuddering episodes were not mentioned in the medical records for seven months after their occurrence. The first report appears in occupational therapy notes from Sensory Connections on August 10, 2000. Pet. Ex. 13, p. 1. Information from Dr. Derrick Lonsdale regarding this shuddering episode was added to the records of W.J.B.'s initial pediatrician (Dr. Wamsley) on February 16, 2001. See Pet. Ex. 1, p. 18. Records from 2001 visits to Dr. Bauer, a developmental pediatrician, and Dr. Wiznitzer, a pediatric

W.J.B.'s aunt, who had phone conversations with Mrs. Blake in February 2000 about W.J.B.'s behavior, did not mention the shuddering episodes in her affidavit, suggesting that they were not matters of concern.

c. According to the medical records filed in this case, W.J.B. has never been diagnosed as having seizures or a seizure disorder.

d. Concerns about W.J.B.'s speech were first raised at a medical visit on February 4, 2000. Based on the physician's indication that he would discuss them with Mrs. Blake at the next scheduled pediatric visit, as opposed to the sick child visit at which they were presented (see Pet. Ex. 1, p. 15), I conclude that the speech concerns were not acute, such as a complete loss of language or cessation of communication during the relevant period. This conclusion is buttressed by petitioners' journal, which records asking for more "milk" on January 12 (Pet. Ex. 16 at 11) and learning the words "more" and "up" on January 18 (*id.* at 12).

e. Despite the fact that petitioners had previously sought medical treatment for ear infections, stuffiness, teething, coughing at night, and URIs, they did not contact a medical professional about W.J.B.'s condition until 27 days after vaccination. At this visit, they did not describe any symptoms consistent with an acute encephalopathy during the period between this visit and the MMR vaccination.

f. The concerns expressed by petitioners in telephone consultations and doctor visits on January 31 and in early February 2000 involved W.J.B.'s recent symptoms of low grade fever, loose cough, runny nose, and lack of appetite (see Pet. Ex. 1, pp. 20-21) and diagnoses of an ear infection and sinusitis (see *id.*, p. 15), not an encephalopathic condition involving loss of responsiveness to his family or environment.

g. W.J.B.'s physician examined him at his February 2000 office visits. W.J.B. was described as alert and playful at the February 1, 2000 office visit. The results of those examinations and descriptions of W.J.B.'s demeanor are inconsistent with the presence of either an acute or chronic encephalopathy, as defined in the QAI.

h. While some symptoms of an ASD either occurred or intensified during January 2000, these symptoms were not of the nature or severity so as to constitute a Table encephalopathy.

i. Video clips taken during the five to fifteen days after the MMR vaccination and, more specifically, the video from January 19, 2000, does not show a child suffering from a Table encephalopathy. Rather, W.J.B. is moving with greater independence during the Gymboree session on January 19, 2000 than during a

neurologist, also mention this incident. See Pet. Exs. 12, p. 1 (February 27, 2001 visit to Dr. Bauer); 6, p. 1 (July 18, 2001 visit to Dr. Wiznitzer).

previous session on November 17, 1999. *Compare* Pet. Ex. 18A at 30:01-32:35 *with id.* at 3:07-6:38. W.J.B.'s activity level, appearance, and interactions conclusively demonstrate that he was not suffering from an acute encephalopathy during the January 19, 2000 session.

j. Journal entries from the five to fifteen days after the MMR vaccination provide no evidence that W.J.B. was suffering from a Table encephalopathy. Instead, the entries depict a child who is alert, interactive, responsive, and learning.

2. Conclusions of Law.

The special master formally assigned to the case repeatedly warned counsel that W.J.B.'s symptoms were not sufficient to establish a Table encephalopathy but more closely resembled symptoms of autism. See Order, issued Oct. 5, 2011, at 1; Order, issued Feb. 15, 2012, at 6; Order, issued Jan. 23, 2013, at 2. After a thorough review of the record, I concur with her conclusions. Given the description of the clinical signs listed in the QAI and the requirement that the symptoms be severe enough to require hospitalization, even if I accepted petitioners' allegations as true, they are insufficient to establish the factual predicate for an acute encephalopathy. Other than descriptions of the shuddering episodes on January 9 and behavior during the Gymboree session on January 19, petitioners have not provided specific instances of symptoms or behavior which occurred during the time period in question.

Their failure to seek any medical attention for W.J.B. during the five to fifteen day period after his MMR vaccination, coupled with their previous visits for mild illnesses, undercuts their claim that he had an injury consistent with a Table encephalopathy during this period. According to their testimony, petitioners did not understand the significance of much of the behavior upon which they rely until later and, thus, they attempt to explain why they did not seek medical attention for W.J.B. during January 2000. However, an acute encephalopathy is a striking and concerning event, and unlikely to be unnoticed at the time it begins.

There is no reliable evidence that W.J.B. experienced an acute encephalopathy, as defined by the Vaccine Injury Table and the QAI, within five to fifteen days of his MMR vaccination. Furthermore, the video, medical, and journal records establish that although W.J.B. may have displayed symptoms of an autistic disorder both before and after his MMR vaccination, he did not manifest a chronic encephalopathy, as defined by the Table, during the six month period following this vaccination.

I hold that W.J.B.'s condition after receipt of the MMR vaccination does not meet the requirements established by the Vaccine Injury Table for a Table encephalopathy.

III. Onset of ASD Symptoms and Actual Causation.

W.J.B. was diagnosed with highly functioning ASD (Asperger's) on July 11, 2000. Pet. Ex. 5, pp. 1, 3. Such a diagnosis necessarily involves behavioral symptoms which may include changes from earlier behaviors.³⁰ Most children later diagnosed with autism spectrum disorders cannot be reliably distinguished from typically developing children before 12 months of age because the behaviors that are associated with autism do not emerge in most cases until the second or third years of life.

Although some autistic behaviors can occur suddenly, they most often manifest over time, and their significance may not be apparent when they first begin. These behaviors may include the loss of skills once demonstrated (a regression), the failure to acquire skills at all or at an age-appropriate time, or the manifestation of stereotypic or abnormal behaviors (such as hand flapping, perseverative behaviors, or a fascination with light switches, ceiling fans, or parts of an object), among many others.

Given W.J.B.'s ASD diagnosis, the fact that W.J.B.'s behavior changed over time is not remarkable or disputed. When specific behaviors began or intensified is significant. For petitioners' actual causation claim, manifestation prior to the allegedly causal vaccination undercuts their claim that the MMR vaccine caused W.J.B.'s condition. And, if petitioners' recollections regarding what happened and when it happened are in conflict with contemporaneously recorded evidence (such as medical records, videos, and journals), I must decide what evidence to credit. To the extent an expert or treating physician relies on evidence that I reject, the opinions of those physicians may become less reliable.

A. Timing of W.J.B.'s Autistic Symptoms.

A thorough review of the evidence shows that W.J.B. exhibited some autistic behavior prior to vaccination. Over time, these behaviors became more intense and apparent while additional behaviors became evident.

Prior to vaccination, Mr. Blake described W.J.B. as being an affectionate and completely normal child with appropriate social interactions and good eye contact. Tr. at 125-26, 133. Mrs. Blake recalled W.J.B. being very interactive, having many play dates and being very involved socially with his family, aware of his surroundings, and aware of the family dog. Tr. at 55-56. Both pointed to a picture of W.J.B. sitting on a car toy with another child as evidence of his normal play and interaction with other children. Tr. at 34-35, 133.

³⁰ See *White v. Sec'y, HHS*, No. 04-337V, 2011 WL 6176064, at *4-9 (Fed. Cl. Spec. Mstr. Nov. 22, 2011) (discussing of the symptoms of and diagnostic criteria for autism under the DSM-IV-TR). The DSM-IV-TR has since been replaced by the DSM-V but the discussion of the symptoms of autism found in *White* is still relevant.

Despite petitioners' assertions, it is clear that, prior to vaccination, W.J.B. was not as interactive and socially involved as petitioners maintain. Because it is difficult to measure social interaction, responsiveness, and eye contact in a still photograph, the pictures highlighted by petitioners provide little support for their claims. The video, however, contains multiple instances prior to vaccination when W.J.B. was playing alone and failed to respond to his parents or others. See Pet. Ex. 18A at 13:52-25:43.

For example, on December 24, 1999,³¹ W.J.B. ignored several of his father's attempts to engage with him. Pet. Ex. 18A at 14:28-16:10. When playing patty-cake with his grandmother, W.J.B. stared at the fireplace through almost the entire segment. *Id.* at 16:14-18:00. Petitioners' video narrative describes this behavior, indicating W.J.B. "seem[ed] to be watching the fire in the fireplace [and didn't] really look at Grandma directly." Pet. Ex. 17 at 4 (emphasis in original). On January 5, 2000, he ignored his father completely, preferring instead to play with the stereo system. Pet. Ex. 18A at 22:10-23:47. That same day, he ignored both parents when playing with magnets on the refrigerator, responding only once when Mrs. Blake asked him what a cow says. During the rest of the video segment, W.J.B. ignored multiple attempts by his parents to get his attention. *Id.* at 24:02-25:41.

With regard to speech delay, W.J.B. was not speaking much prior to vaccination. As evidenced on the video submitted, W.J.B.'s speech ability is fairly consistent; at all times, he spoke little, saying a word or making a sound rarely, if ever. Watching the video from November 17, 1999 (prior to vaccination), I do not hear the verbalization petitioners described in their notes, nor do I see the "rich non-verbal communication" they reference. *Compare* Pet. Ex. 18A at 3:50-6:45 *with* Pet. Ex. 17 at 2.

From the evidence submitted, W.J.B. showed a decreased level of eye contact, responsiveness, speech and social interaction prior to receiving the MMR vaccine. Clearly, these autistic symptoms were not caused by the MMR vaccine.³² Even so, I will discuss the evidence needed to prove vaccine causation and determine if petitioners have met their burden in this case.

B. Legal Requirements for Demonstrating Vaccine Causation.

The Federal Circuit has set forth three factors petitioners must establish to prove causation in off-Table cases. See *Althen*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). *Althen* requires petitioners to provide: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship

³¹ The date is derived from Mr. Blake's remark on the video that it was Christmas Eve.

³² Petitioners have not asserted a significant aggravation claim, nor is there any evidence in the record before me that such a claim would be tenable.

between vaccination and injury.” *Id.* All three prongs of the *Althen* test must be satisfied by preponderant evidence. *de Bazan v. Sec’y, HHS*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Caves v. Sec’y, HHS*, 100 Fed. Cl. 119, 132 (2011), *aff’d per curiam*, 463 Fed. Appx. 932, 2012 WL 858402 (Fed. Cir. 2012) (finding that “[w]hen a petitioner seeks to demonstrate causation in fact by meeting the three *Althen* requirements, each of those requirements must be proven by a preponderance of the evidence”).

Petitioners may satisfy this evidentiary burden by relying either on “medical records or medical opinion.” *Althen*, 418 F.3d at 1279 (emphasis in original). Causation is determined on a case by case basis, with “no hard and fast *per se* scientific or medical rules.” *Knudsen v. Sec’y, HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. *But see Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof fails to meet that burden).

1. Lack of a Reliable Medical Theory.

To satisfy the first prong of the *Althen* test, petitioners must provide “a medical theory causally connecting the vaccination and the injury.” *Althen*, 418 F.3d at 1278 (quoting *Grant v. Sec’y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The medical theory must be a reliable one. *Knudsen*, 35 F.3d at 548 (“This ‘logical sequence of cause and effect’ must be supported by a sound and reliable medical or scientific explanation.”). Petitioners must prove the existence of this medical theory by a preponderance of the evidence. *Broekelschen v. Sec’y, HHS*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). In other words, petitioners must show that it is more likely than not that the received vaccine **can** cause the alleged injury. *Pafford*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (emphasis added).

In this case, petitioners have failed to proffer any theory explaining how the MMR vaccination can cause an encephalopathy manifesting as autism. Instead, they simply claim that “[t]he Table itself provides the medical theory that the MMR [vaccine] can cause an encephalopathy.” Pet. Reply at 4. Petitioners are conflating Table and non-Table injuries. Having failed to establish a Table injury claim, petitioners cannot rely on the Table.³³ Rather, petitioners must satisfy the first test in proving causation by setting forth a reliable medical theory.³⁴ They have failed to do so.

³³ “Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner.” *Grant v. Sec’y, HHS*, 956 F.2d at 1148 (quoting H.R.REP. NO. 99–908, 99th Cong., 2d Sess., pt. 1, at 15 (1986), *reprinted in* 1988 U.S.C.C.A.N. 6344, 6356).

³⁴ An impressive body of medical and scientific evidence regarding the claim that the MMR vaccine could cause ASDs was adduced in the OAP Theory 1 test cases, with the three special masters who heard this evidence concluding that the issue of MMR causation was not a “close call.” *Cedillo*, 2009 WL 331968, at *135; *Hazlehurst*, 2009 WL 332306, at *172; *Snyder*, 2009 WL 332044, at *198. Each special master independently determined that the medical theories advanced were not reliable and that the test case petitioners had failed to produce preponderant evidence that the MMR vaccine could cause ASDs.

2. Lack of a Logical Sequence of Cause and Effect.

Even if petitioners had provided a theory which satisfied the first prong, to satisfy the second prong of the *Althen* test, petitioners must establish a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” *Althen*, 418 F.3d at 1278. In other words, petitioners must show that the received vaccine actually caused the alleged injury. *Pafford*, 451 F.3d at 1356. The sequence of cause and effect need only be “logical and legally probable, not medically or scientifically certain.” *Knudsen*, 35 F.3d at 548-49; accord. *Capizzano v. Sec’y, HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). Testimony from a treating physician may assist petitioner in meeting her burden of proof under the second *Althen* prong. *Capizzano*, 440 F.3d at 1326.

Petitioners contend Dr. Erenberg’s statement, indicating W.J.B. experienced “some form of encephalopathic pattern of change” (Pet. Ex. 2, p. 2.), is sufficient proof of a logical sequence of cause and effect, but this statement is far from being sufficient. In that same report, Dr. Erenberg added “it would be impossible to figure out what [the causal] event might have been.” *Id.*

Although Dr. Erenberg expressed his opinion that W.J.B.’s encephalopathic event “might have been due to a viral infection” in a “to whom it may concern letter” written that same day, this general statement also is insufficient to implicate the MMR vaccination. The MMR vaccine is a “combined live virus vaccine” (Pet. Reply at 4) as petitioners contend, but Dr. Erenberg never mentions the MMR vaccination as a possible cause or opines that it could have caused the “encephalopathic pattern of change” to which he refers. Moreover, as also noted by the special master formerly assigned to this case, Dr. Erenberg did not examine W.J.B. during this “encephalopathic event” but 18 months later. See Order, issued Feb. 15, 2012, at 6.

In addition to failing to satisfy the first *Althen* prong, petitioners have failed to meet the requirements of the second prong.

3. Lack of a Temporal Relationship.

When proving that a vaccine was the cause of an injury, petitioner must also show “a proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278. Petitioner must prove “that the onset of symptoms occurred within a

Although the petitioners in this case were part of the OAP, they are not bound by the results in the Theory 1 test cases. *Snyder*, 2009 WL 332044, at *2-3. Nevertheless, they have advanced no new evidence—indeed, no evidence at all—suggesting that the result reached in the Theory 1 test cases was incorrect. I agree with the special master who earlier advised them that, without new evidence not considered in the test cases supporting their causation theory, continuing to advance an MMR causation theory was unreasonable. Order, issued Feb. 15, 2012, at 7.

timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y, HHS*, 539 F.3d at 1352. Failure to provide a proximate temporal relationship will result in a denial of compensation. *Id.* at 1353.

Petitioners' expert, Dr. Cave, provided no evidence supporting vaccine causation other than arguing that a comparison of the timing of W.J.B.'s viral illness (which she claims occurred at least eight days before onset) makes it is "more likely than not that the encephalopathic change in [W.J.B.] occurred because of the MMR (live viral) vaccine given five days prior to the onset of the problem." Pet. Ex. 15 at 2. However, as the Federal Circuit has indicated, timing alone is not sufficient to prove causation. *Grant*, 956 F.2d at 1148.

Furthermore, as I previously stated, I do not accept petitioners' assertions that W.J.B.'s symptoms began within five to fifteen days of vaccination. I also do not attribute great weight to Dr. Cave's opinion as she lacks expertise in the specialties relevant to the issues in this case. See Order, issued Feb. 15, 2012, at 1-2 (noting Dr. Cave lacks expertise in developmental pediatrics, pediatric neurology, and pediatric immunology).

4. Conclusion on Actual Causation Claim.

Petitioners have failed to establish any of the *Althen* factors by preponderant evidence. Thus, petitioners have failed to prove that the MMR vaccine W.J.B. received on January 4, 2000 actually caused his ASD.

VI. Conclusion.

Petitioners have asserted both that W.J.B. suffered a "Table" injury and that a vaccine listed on the Table was the cause in fact of W.J.B.'s injuries but have failed to prove either claim. After considering the record as a whole, I find that petitioners have failed to establish entitlement to compensation. The petition is dismissed. The clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Chief Special Master